## EUREQ7 07/21/00

## EXPORT REQUIREMENTS FOR THE EUROPEAN UNION

The United States and the European Union (EU) have reached a bilateral agreement on the export and import of animals and animal products. The conditions for the export of U.S. meat and poultry and meat and poultry products to the EU are part of this agreement, which become effective upon implementation of the "Veterinary Equivalency Agreement." These requirements become effective August 1, 1999.

The EU member countries are Austria, Belgium, Denmark, Finland, France, Germany, Greece, Italy, Ireland, Luxembourg, the Netherlands, Portugal, Spain, Sweden, and the United Kingdom.

Finland and Sweden have additional requirements. See Section XIV for more information.

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### I. ELIGIBLE PRODUCTS

The products defined below are eligible for export to the European Union provided that the

production systems used to produce them and all pertinent EU requirements are met.

- A. "Meat" means all parts of domestic bovine animals (including bison), swine, sheep, goats, and solipeds which are suitable for human consumption.
- B. "Fresh meat" means meat, including meat vacuum-wrapped or wrapped in a controlled atmosphere, which has not undergone any treatment other than cold treatment to ensure preservation.
- C. "Poultrymeat" means all parts fit for human consumption from domestic birds of the following species: domestic fowl, turkeys, guinea fowl, ducks and geese.
- D. "Fresh poultrymeat" means poultrymeat, including meat which is vacuum-wrapped or wrapped in a controlled atmosphere, which has not undergone any preservation process other than chilling or freezing.
- E. "Offal" means fresh meat and fresh poultrymeat other than that of the carcass, even if it remains naturally connected to the carcass.
- F. "Meat preparations" means meat (from carcasses, offals, poultrymeat, minced meat, wild game, or rabbit) which have had foodstuffs, seasonings or additives added to them; or which have undergone a treatment insufficient to modify the internal cellular structure of the meat and, thus, does not cause the characteristics of the fresh meat to disappear.
- G. "Meat products" means products prepared from or with meat, including poultrymeat, which has undergone treatment such that the cut surface shows that the product no longer has the characteristics of fresh meat. The following are <u>not</u> meat products: meat which has undergone only cold treatment and products such as minced meat, meat in pieces of less than 100 grams, and meat preparations.
- H. "Minced meat" means meat which has been minced into fragments or passed through a spiral-screw mincer.
- I. "Other products of animal origin" are (1) meat extracts; (2) rendered animal fat: fat derived from rendering meat, including bones, and intended for human consumption; (3) greaves: the protein-containing residue of rendering, after partial separation of fat and water; (4) gelatin; (5) meat powder, powdered rind, slated or dried blood, salted or dried blood plasma; and (6) stomachs, bladders and intestines, cleaned, salted or dried, and/or heated.
- J. "Farmed game" means land mammals or birds which are not considered as domestic and are not referred to in the definitions of meat or poultrymeat, but which are farmed as domestic animals.
- K. "Wild game" means wild land mammals which are hunted (including wild mammals living

within an enclosed area under conditions of freedom similar to those enjoyed by wild game) and wild birds which are not covered by the EU farmed game meat directive.

### II. FACILITY, EQUIPMENT, AND PROCEDURAL REQUIREMENTS

Meat and poultry establishments must be under FSIS inspection in order to be eligible for export to the EU. The following requirements are in addition to FSIS domestic requirements or, if a domestic requirement, an area of special emphasis in the US/EU agreement.

## A. Packaging material

- 1. Packaging material shall be kept in separate rooms that are used exclusively for this purpose and free of dust and vermin.
- 2. Packaging material shall not be stored on the floor.
- 3. Waxed assembled boxes shall not be nested, unless a liner will be added prior to filling.
- 4. Assembled boxes with liners shall not be nested.
- 5. Boxes shall not be handled by personnel who are handling exposed product.
- 6. Boxes shall be assembled in a sanitary manner, either in a separate room or, if in the processing room, never within 3 meters of exposed product.

## B. Facility requirements for walls and floor junctions

- 1. Walls shall be smooth, durable, impermeable, and of a color which permits detection of insanitary conditions.
- 2. Walls shall have washable surfaces.
- 3. Walls and floor junctions shall be constructed and maintained so as to assure that surfaces are clean and free of contamination. Establishments that do not use cove molding to provide a smooth transition from floor to wall to facilitate cleaning must provide an equivalent alternative means, such as sealing of cracks between walls and floors, to maintain sanitary conditions.
- C. Pallets in exposed product areas The use of wooden pallets in areas where there is exposed product shall be phased out. Until such time:
  - 1. No wooden pallets shall be used within 3 meters of exposed product.
  - 2. All pallets shall be clean and structurally sound.
  - 3. Wooden pallets shall be covered with a sanitary plastic slip sheet covering the entire top of the pallet.
  - 4. Those establishments which are already using plastic pallets shall continue to do so.
  - 5. When wooden pallets are used in coolers or freezers, all product present shall be hygienically packaged to prevent contact of product with wood.

## D. Separation of lavatories and work areas

Toilet rooms shall be properly ventilated and shall be separated from exposed product rooms by either a vestibule or a dressing room.

### E. Dry storage of non-food material

Detergents, disinfectants and similar substances shall be stored separately from food and from wrapping and packaging material.

### F. Waste water

All establishments shall have an efficient drainage and plumbing system, and all drains and gutters shall be properly installed with traps and vents approved by FSIS, in accordance with 9 CFR 308.3(c) and 9 CFR 381.49(a),(c).

## G. Separate storage of edible and inedible products

Condemned and other inedible meat and offal shall be removed in a hygienic manner, and as quickly as possible, from rooms containing edible material.

## H. Separate storage of packaged and unpackaged products

Unpackaged exposed meat may not be stored in chilling or freezer rooms containing packaged meat.

#### I. Structural wood

Wooden structures shall be in good condition, impermeable, smooth, durable, rot-proof and sealed with a waterproof coating.

- J. Use of suspended showers, sprays and hoses
  - 1. Such devices shall not be used as a substitute for handwashing facilities.
  - 2. Meat shall not be contaminated by splashing.

## K. Sterilization of utensils and implements

Establishments shall provide sterilization equipment (batch or local sterilizers) to clean utensils as often as necessary. Implements such as knives or hooks which come into contact with meat shall be cleaned and sterilized frequently, and whenever they have been in contact with contaminated material or surfaces such as the external surfaces of hides. Sterilization shall be done with >180°F (82°C) water.

## L. Accommodation for sick and suspect animals

- 1. Wood shall not be used for pens for sick and suspect animals.
- 2. Sick and suspect animals shall not be allowed to come into contact with animals intended for slaughter for export to the EU.
- 3. Pens for sick and suspect animals shall be sited and constructed to preclude contact with animals intended for slaughter for export to the EU, and effluent from such pens shall not flow into adjoining pens or passageways.

### M. Opening of stomachs and intestines

There must be a separate room for emptying and cleaning stomachs and intestines, unless the

processing is done by closed-circuit mechanical equipment which avoids contamination and eliminates odors.

### N. Batch condemnation

If carcasses, offals and blood are not correlated at the final postmortem inspection point, a batch system shall be operated in such a way that the Inspector in Charge (IIC) can demonstrate that if a carcass is condemned its offal and blood shall also be condemned.

### III. EMPLOYEE MEDICAL CERTIFICATION

A. Prior to employment, new employees shall be examined and certified by a medical doctor or by a person with appropriate medical training (e.g. a physician's assistant or a registered nurse) working under the supervision of a medical doctor. The EU does not mandate specific disease testing (e.g. hepatitis, tuberculosis, etc.) Specific disease testing is left up to the professional judgement of the medical professional that is signing the certification. Acceptable terminology for the medical certification would be: "Having examined (employee name) on (date), it is my opinion that he/she is not suffering from any condition that would render him/her unfit to work with meat or meat products."

- 1. Establishments shall have in place an appropriate program to continuously monitor employee health by one of the health professionals described in A.
- 2. All cases of suspected diseases shall be referred to a medical doctor for diagnosis.
- 3. Establishments shall keep records of medical examinations and shall make those records available to auditors upon request.
- 4. The medical certification requirement only applies to those employees who handle exposed product.

### IV. WATER TESTING

Pending EU review of the U.S. water standards, water testing shall be carried out as follows:

A. The initial water testing requirements are as follows:

Test	Sample size	Temp.	Maximum conc.
Total coliforms	100 ml	37° C	Membrane filter - 0 or MPN < 1
Fecal coliforms	100 ml	37° C	Membrane filter - 0 or MPN < 1
Fecal strep	100 ml	37° C	Membrane filter - $0$ or MPN < $1$
Sulphite-reducing	20 ml	37° C	MPN < 1
Clostridia			
Total Plate Count	1 ml	37° C	Guide level - 10
	1 ml	22° C	Guide level - 100

## B. Subsequent water testing

1. Frequency:

- a. Annually, if municipal source of water and no intermediate storage in the plant.
- b. Monthly, if private source of water or intermediate storage is used
- 2. Two examinations are required:
  - a. Total plate count at 37° C and 22° C incubated for a minimum of 72 hours,
  - b. and total coliform at 37° C incubated for a minimum of 48 hours.
- 3. Sampling
  - a. Samples must be taken from randomly selected water taps within establishments.
  - b. A diagram of tap locations and log of which taps have been sampled should also be maintained.
- 4. Test results

If test results are not within the required parameters, immediate retesting must be done. The retesting requirements are the same as the initial testing requirements.

5. Chlorination testing

A daily chlorination test is required if the private water supply or plant water supply is chlorinated for potability

C. Water testing requirements do not apply to cold storage facilities where only packaged meat is handled.

### V. ANTEMORTEM INSPECTION

Antemortem inspection will be performed by FSIS in accordance with 9 CFR 309 and according to FSIS procedures.

### A. Cattle

- 1. Cattle under 30 months of age:
  - a. Inspection by an FSIS veterinarian or;
  - b. Antemortem inspection may be performed by an official FSIS inspector with appropriate training, knowledge, skills and abilities provided that:
    - (1) the animals originate from a premise where an APHIS accredited veterinarian is present on an ongoing basis, and
    - (2) a letter from the premise confirming such presence must be on file at the plant.
- 2. Cattle over 30 months of age must be inspected by an FSIS veterinarian.

### C. Swine

- 1. Swine under 1 year of age will be inspected by FSIS in accordance with FSIS procedures.
- 2. Swine over 1 year of age must be inspected by an FSIS veterinarian.
- E. All animals demonstrating abnormal signs shall be diagnosed and disposed of by an FSIS veterinarian.

#### VI. PIG HEART INCISION

- A. For market hogs (animals up to 1 year old), the following number of swine hearts from inspected and passed carcasses at each approved slaughter establishment must be incised and their interior surfaces inspected by the IIC:
  - 1. Six (6) hearts per establishment per week (or a rate to yield 300 hearts/establishment/year) must be incised and their interior inspected. IICs should randomly select one time per week to conduct the inspection. During this time, 6 hearts should be randomly selected. Each of the hearts should be laid open for examination of the endocardium in all chambers and associated valves. Although the best location for conducting the inspection may vary from plant to plant, an appropriate location may be in the offal packing area near or at the heart washer exit.
  - 2. Gross pathological lesions, including lesions of endocarditis, should be described on the EU Pork Heart Weekly Data Sheet included as Attachment 1. Negative findings should also be recorded on a weekly basis. The Data Sheets should be maintained on file in the inspection office. Plant management should submit copies of the Data Sheets to the Export Staff of the Technical Service Center on a quarterly basis.
- B. For sows and boars (animals over 1 year of age) from which meat or offal destined for the EU is produced, each heart must be incised and its interior surfaces inspected by FSIS personnel. Procedures have not been developed to conduct this inspection. Therefore, meat and offal from these animals cannot be exported to the EU at this time.

### VII. TRICHINAE

- A. Pork meat and horsemeat shall be subjected to cold treatment according to 9 CFR 318.10 OR
- B. each pork or horse carcass shall be tested for trichinae at the time of slaughter. Testing requires the following elements:
  - 1. The laboratory performing the tests must participate in the USDA, Agricultural Marketing Service (AMS) Trichinae Analyst and Laboratory Certification Program. For further information about this program, contact AMS:

Isaac Sterling (202) 720-5898 Chemist, USDA, AMS, STD, TSB P.O. Box 96456, Room 3517-South 14th & Independence Avenue, S.W. Washington, DC 20090-6456

- 2. Each establishment must have a written program and procedures in place that assures that only product from carcasses that have tested negative for trichinae are certified for export as such. This program must include sampling procedures, testing procedures according to the AMS program, as well as non-cominglement procedures throughout slaughter, fabrication, processing, and packaing.
- 3. The IIC will review the establishment's written control program to determine if it is adequate to maintain controls. FSIS inspection personnel will perform random checks of these procedures in operation as well as checks of the records maintained by plant management. If problems are observed in the program during the checks, the Export staff at the Technical Service Center should be notified through supervisory channels. Meat produced during this time should not be certified for export to the EU.

### VIII. ANTIMICROBIAL TREATMENTS

Antimicrobial treatments (for example, hyperchlorination, TSP, organic acids, etc) are not allowed for treatment of red meat or poultry carcasses, parts or viscera. Only the application of water or steam is permitted.

### IX. POULTRY CHILLING:

- A. Immersion chilling of carcasses must meet the following requirements:
  - 1. Carcasses must move through the chiller against a counterflow of water.
  - 2. Recirculation of chiller water is not allowed.
  - 3. The temperature of the water in the chiller must not exceed 61°F at the carcass entry and 40°F at the carcass exit.
  - 4. The following amounts of water are required per bird:

Bird size	Inside/outside washer	<u>chiller</u>
<5.5 lb	0.40 gal	0.65 gal
5.5 to 11 lb.	0.65 gal.	1.00 gal.
> 11 lb.	0.90 gal.	1.50 gal.

- 5. Water consumption during carcass washing and immersion chilling, temperature of the water at the entrance and exit points of the chiller, and the number of carcasses in each weight range must be measured and recorded.
- B. Alternative chilling systems to IX.A.1-5. may be used if they demonstrate a decreased microbial load for: aerobic plate counts; enterobacteriaceae; and E. coli before and after chilling. FSIS will validate and assess the data before the establishment is proposed for listing for export to

the EU. This validation and assessment shall be carried out without the use of antimicrobial treatment, throughout a full day's production.

During the course of the day, plant management should select 30 or more carcasses prior to entry into the chiller and the same number of carcasses at the exit of the chiller. Samples should be taken randomly throughout a day's production. Whole bird rinses should be used for sample collection. Analysis of samples should be done using an AOAC International approved method. Plant management should submit a report of the assessment and results to the Export Staff of the Technical Service Center.

This assessment shall be carried out each time any changes are made to a plant's chilling system. Records shall be kept of the validation and assessments, and shall be available to the EU.

## C. Poultry temperature requirements

- 1. Poultry shall be chilled to an internal temperature of  $40^{\circ}$  F in the shortest time possible after slaughter.
  - a. In the case of small birds (up to 6 pounds), the internal temperature of  $40^{\circ}$  F shall be achieved by the end of the immersion chilling process.
  - b. Where crushed ice is used to chill large birds (over 6 pounds) after immersion chilling, such use must not result in cross contamination of the product. The use of boxes with leak holes for this purpose is not acceptable. Tanks or vats such as those specified in 9 CFR 381.66 (c) (4) (ii) should be used.
- 2. When further processing (cutting) occurs after poultry has been chilled to  $40^{\circ}$  F, the internal temperature may exceed  $40^{\circ}$ F for a maximum of one hour, but may not exceed  $50^{\circ}$  F.

### D. Crushed ice

1. The use of crushed ice must not result in cross contamination of the product. When crushed ice is used for further transport or storage, stacking of boxes with leak-holes or other practices which could result in cross contamination shall be prohibited.

#### X. RESIDUE TESTING

EFFECTIVE March 31, 2000, and until further notice, analyses for DES, hexestrol, dienestrol, zeranol, taleranol, trenbolone, 19-nortestosterone, clenbuterol, salbutamol, cimaterol, chloramphenicol, azaperone, propionylpromazine, and carazolol will be sent to RIKILT-DLO in Wageningen, the Netherlands.

- A. All slaughter establishments approved for export of meat and/or offals to the EU are required to participate in the EU Additional Residue Testing Program.
- B. The cost of analysis is the responsibility of the establishment management. Questions concerning analytical costs may be addressed directly to the laboratories participating in the program.

Any laboratory conducting analytical residue chemistry for the EU additional residue testing program is required to participate in Agricultural Marketing Service's European Meat Export Laboratory program, which provides technical assistance, analytical and monitoring components to assess and oversee the analytical performance of each laboratory For additional information on this program, laboratories should contact AMS, Science and Technology Division, Technical Services Branch, Washington, D.C. at (202) 690-0621.

C. The species, target compounds, and numbers of samples to be collected are listed in the table below. The targeted number of samples for each species is based on the total number of head slaughtered by all EU approved establishments of the species from the previous year. The number of samples to be collected at each establishment will be predicated by the number and the volume of EU destined product slaughtered.

2000 EU Additional Testing Program									
Target Number of Samples for Compound/Species									
Group of	Substances Target Number of Animals to be Sampled 2/						d 2/		
Substances 1/		Equine	Equine   Pork		Beef			Game	
				Steers Heifers	Veal	Cows Other Bovine	Wild	Farmed /3	
Group A									
Substances having a	nabolic effect and	unautho	rized su	bstances	<u> </u>				
1. Stilbenes	DES	85	30	4	0	4	-	-	
	Hexestrol	85	30	4					
	Dienestrol	85	30	4					
2. Antithyroid	Thyrostats	125	30	4	0	-	-	-	
Agents	(2-thiouracil)								
3. Steroids	MGA	-	-	6	-	-	-	-	
	19-	40	30	6	0	4	-	-	
	Nortestosterone								
	(17-∃)								
	19-	-	-	6	-	-	-	-	
	Nortestosterone								
	(17-∀)								
	Trebolone	40	30	6	0	4	_	-	
4. Resorcyclic acid	Zeranol	85	30	4	0	2	-	-	
Lactones	Taleranol	85	30	4		2			
5. Beta-agonists	Clenbuterol	85	30	2	-	2	-	-	
	Cimaterol	85	30	2		2			
	Salbutamol	85	30	2		2			
	Ractopamine *	-	30	2		2			

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3/

Farmed

Wild

6. Unauthorized	Nitrofurans	125	30	4	-	4	-	-
compounds	Nitrofurazone							
	Furazolidone							
	Furaltadone							
	Nitroimidazoles	-	30	-	-	-	-	-
	Dimetridazole							
	OH-imidazole							
	Chloramphenicol	125	30	4	-	4	-	-
Group B								
Veterinary Drugs an	nd Contaminants							
Group of	Substances	Target Number of Animals to be Sampled 2/				d 2/		
Substances 1/		Equine	Pork		Beef		G	ame

Veal

Cows

Other Bovine

Steers

Heifers

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							Page 1.	2 01 31
1. Antibacterial		-	-	-	-	-	-	-
substances								
2. Other veterinary		-	-	-	-	-	-	-
drugs								
(a) Anthelmintics		-	-	-	-	-	-	-
(b) Anticoccidials		-	-	-	-	-	-	-
(c) Carbamates		-	-	-	-	-	-	-
(d) Sedatives	Azaperone	-	30	-	-	-	-	-
	Propriopromazine		30					
	Carazolol		30					
(e) Non-steroidal		-	-	-	-	-	-	-
anti-inflammatory								
drugs (NSAIDs)								
(f) Other		-	-	-	-	-	-	-
pharmacologically								
active substances								
3. Other substances		-	-	-	-	-	-	-
and								
environmental								
contaminants								
(a) Organochlorine		-	-	-	-	-	-	-
compounds								
(b)		-	-	-	-	-	-	-
Organophosphorous								
compounds								
(c) Chemical	Cadmium	125	30	5	-	5	6	
elements	Lead	125	30	5	-	5	6	
(d) Mycotoxins		-	-	-	-	-	-	-
(e) Dyes		-	-	-	-	-	-	-
(f) Other		-	-	-	-	-	-	-
TOTAL		1385	570	106			12	
SAMPLES								
TARGETED			1	1				

1/ Grouping based on Directive 96/23/EC

2/ Sample frequency is based on 1999 slaughter figures for EU production. If product increases significantly during the year, sample frequencies will be adjusted accordingly.

Residue testing for farmed game is under review by the Food and Drug Administration.

- D. Each EU approved slaughter establishment must address or fax a letter designating the laboratory of choice for each compound to the Technical Service Center, Import/Export Staff [facsimile number: (402) 221-7479.] Sample request forms (FSIS form 10,210-3) will be preprinted and sent directly to the FSIS Inspector-in-charge (IIC) at the EU approved slaughter establishment periodically throughout the year. These forms will designate the date samples are to be collected (within 30 days of the specified date), tissue to be collected, the code for the residue which will be analyzed, and the laboratory designated to perform the analysis.
- E. The IIC is responsible for collecting, securing and freezing the samples. These samples will be sent to the designated lab via overnight express mail in containers provided by the slaughter establishment, at the expense of the slaughter establishment. Sample selection and shipment of the samples cannot be delegated to plant management. When samples are sent out of the United States for analyses, plant management must use a company that will deliver perishable products in a timely fashion and must provide International airbills. To avoid unnecessary delays, include all appropriate documents for entry into the country where the samples are destined.
- F. Any questions related to the EU Additional Residue Testing Program should be directed to the Technical Service Center, Residue Operations Staff or the Export Staff at (402) 221-7400 or (800) 233-3935.

# XI. NON-HORMONE TREATED CATTLE (NHTC) PROGRAM: BEEF AND VEAL (formerly referred to as the Hormone Free Cattle (HFC) programs)

All bovine meat exported to the European Union must originate from animals that have never been treated with hormonal growth promotants. In order for FSIS to provide export certification for this product, there must be assurances that there are effective controls in all phases of production, from birth to slaughter, and subsequent processing and final packaging activities.

Producer affidavits supplied by the grower, producer, and feeder will provide assurances that each individual animal in the entire lot of cattle presented for slaughter has never been fed or treated with hormonal growth promotants. Each phase of the production of these animals will maintain a written control program that describes the procedures for maintaining identity of and segregating non-hormone treated cattle, as well as the controls that are in place to prevent the administration of restricted compounds to the animals. The documented system will be audited by the Agricultural Marketing Service (AMS), Livestock and Seed Program or by an AMS-accredited independent third party system. Contact the AMS Meat Grading and Certification Branch at (202) 720-1113 for additional information regarding this program. AMS Website.

Guidelines have been developed for the industry by FSIS, which provide the system requirements and expected components of the program (FSIS' Program for Certifying Non-hormone Treated Beef to the European Union.) AMS has developed instructions providing the general policies and procedures for providing service under the NHTC Program. See documents prepared by AMS, Meat Grading and Certification Branch (MGCB): "MGC Instruction 708," "Live Animal

Production Guidelines, " and "Slaughter Fabrication Guidelines" at the <u>NHTC Web Page</u> provided by AMS. Contact FSIS Technical Service Center, Export Staff at (402) 221-7400, if necessary, for a copy of these documents.

## A. Beef and veal production

- 1. Each phase of the production of these cattle, from birth to slaughter, must receive third party verification prior to FSIS certifying NHTC to the EU.
- 2. Each lot of cattle presented to the slaughter establishment must be accompanied by a signed producer affidavit certifying that the animals have never been treated with hormonal growth promotants. (Example of Producer Affidavit)
- 3. All cattle must be slaughtered and processed in a federally inspected establishment approved for production of products destined for the EU.
- 4. Each establishment must have a written program and procedures in place that will assure the production and shipment of product derived from animals that have never been administered hormonal growth promotants. AMS (or an AMS accredited independent third party) will review program documentation for beef slaughter operations to ensure adequacy and continuity of product control and identification procedures.

## B. Dairy/breeding cow product production

Pending further discussion with the EU, cow meat and cow offal will not be eligible for export to the EU unless it is produced according to the NHTC program guidelines referenced above.

### C. In-process Controls

Each establishment involved in the production of NHTC beef must maintain documentation in accordance with an approved written control program and follow procedures that will assure the production and shipment of product derived from non-hormone treated cattle. Mandatory in-plant controls include:

- 1. Plant management must maintain documents to record the number of animals presented for slaughter and the number of animals slaughtered under EU mode of production.
- 2. Product destined for the EU must be appropriately identified and segregated throughout production according to the establishment's written control program.
- 3. Slaughter establishments must perform 100% palpation of the ears for hormone implants of all cattle or veal to be slaughtered under the NHTC program. This is to be done with the oversight of the FSIS/IIC.
- 4. Slaughter establishments must issue an affidavit confirming the non-hormone treated status of meat shipped to cutting plants without an EU Health Mark applied in a tamper evident fashion (Example of Transfer Affidavit). Adequate records supporting control of product transferred to separate processing facilities and cold storage warehouses must be maintained by plant management.

## D. FSIS Inspector-in-Charge Responsibilities (<u>IIC Procedures</u>)

The IIC will verify that the establishment's written control program has been reviewed by AMS to determine if it is adequate to maintain product and identification controls throughout the slaughter, fabrication, processing, packaging process, to the point that the EU Health Mark is

applied in a tamper evident fashion. FSIS inspection personnel will perform random checks of these procedures in operation throughout the EU production, as well as checks of the records maintained by plant management. In addition, FSIS will check company records, when necessary, to verify proper transfer for subsequent storage prior to certification of the product to the EU. Compliance oversight by FSIS includes:

- 1. Familiarity with the establishment's written control program.
- 2. Verification that the NHTC lot comes from an AMS approved premise. The affidavit will be reviewed to confirm that it complies with the parameters outlined in the establishment's written control program, including animal identification and authorized affidavit signer controls. Cattle arriving at the slaughter establishment without adequate identification or certification (producer affidavit) will not be permitted to be slaughtered for the EU until the deficiency is corrected according to the company's control procedures.
- 3. Sampling every lot of cattle presented for slaughter destined to the EU for the "Special Residue Testing Program for NHTC."
- 4. Performing additional random procedures to determine compliance with the program. Procedures will include all aspects from receiving through shipping and may include observation, review of records, or both. All records from an entire lot of product will be reviewed on a periodic basis. Reviewed records will be signed and dated.
- 5. If there is noncompliance with EU requirements or with the establishment's control program, the IIC will notify management and request correction of the deficiency. If a deficiency is not corrected, the IIC will withhold the EU health mark label (or brand). The labels (or brand) will be returned to the IIC and secured until correction is made. The IIC will document the noncompliance.
- 6. If repeated deficiencies occur, or a non-compliance is not corrected in a reasonable time period, the Export staff at the Technical Service Center shall be notified through supervisory channels.

## E. Special Residue Testing Program for the NHTC Program

In addition to the monitoring samples collected under the EU Additional Residue Testing program, NHTC will be subjected to intensified testing for specific hormonal growth promotant compounds. Effective May 3, 1999, and until further notice, every lot of cattle presented for slaughter destined to the EU will be subjected to analytical testing for measurable levels of melengestrol acetate (MGA), zeranol, and trenbolone. The laboratory must confirm any detected level, including traces. The cost of these analyses will be the responsibility of the industry

### XII. PORK FOR THE EUROPEAN UNION (PFEU) PROGRAM \*

All pork exported to the EU must originate from animals that have never been treated with hormonal growth promotants. In order for FSIS to provide export certification for this product, there must be assurances that there are effective controls in all phases of production in growing the animal, as well as at the slaughter establishment. FSIS has developed guidelines for the industry, which provide the system requirements and components of the program (<a href="Program for Certifying Pork Intended for Export to the EU">Program for Certifying Pork Intended for Export to the EU</a>). Though each phase of production (or ownership stage) will have to demonstrate that their system controls are adequate, emphasis will be placed on the controls at the finishing unit to

ensure ractopamine hydrochloride (ractopamine) is not fed. The documented system will be audited by AMS (or by an AMS-accredited independent third party). AMS has developed instructions providing general policies and procedures for providing services under the PFEU Program MGC Instruction 710, Pork to the European Union Program (not yet available, to be posted on AMS' Web site). Contact the Technical Service Center, Import/Export Staff at (402) 221-7400 for a fax copy of these documents.

## A. Pork production

- 1. Pork production systems finishing hogs for the production of meat intended for export to the EU must receive third party verification.
- 2. Each lot of hogs presented to the slaughter establishment must be accompanied by a signed producer affidavit certifying that the animals have never been fed ractopamine. (Example of Pork Producer Affidavit)
- 3. All hogs must be slaughtered and processed in a federally inspected establishment approved for production of products destined for the EU.
- 4. Each establishment must have a written program and procedures in place that will assure the production and shipment of product derived from animals that have never been administered hormonal growth promotants. AMS (or an AMS accredited independent third party) will review program documentation for pork slaughter operations to ensure adequacy and continuity of product control and identification procedures.

### B. In-process Controls

Each establishment involved in the production of pork must maintain documentation in accordance with an approved written control program and follow procedures that will assure the production and shipment of product derived from hogs that have not been fed ractopamine. Mandatory in-plant controls include:

- 1. Plant management must maintain documents to record the number of animals presented for slaughter and the number of animals slaughtered under EU mode of production.
- 2. Product destined for the EU must be appropriately identified and segregated throughout production according to the establishment's written control program.

### C. FSIS Inspector-in-Charge Responsibilities (Pork IIC Procedures)

The IIC will verify that the establishment's written control program has been reviewed by AMS to determine if it is adequate to maintain product and identification controls throughout the slaughter, fabrication, processing, packaging process, to the point that the EU Health Mark is applied in a tamper evident fashion. FSIS inspection personnel will perform random checks of these procedures in operation throughout the EU production, as well as checks of the records maintained by plant management. In addition, FSIS will check company records, when necessary, to verify proper transfer for subsequent storage prior to certification of the product to the EU. Compliance oversight by FSIS includes:

- 1. Familiarity with the establishment's written control program.
- 2. Verification that the PFEU lot comes from an AMS approved premise. The affidavit will be reviewed to confirm that it complies with the parameters outlined in the establishment's written control program, including lot identification and authorized affidavit signer controls. Hogs arriving at the slaughter establishment without adequate

identification or certification (producer affidavit) will not be permitted to be slaughtered for the EU until the deficiency is corrected according to the company's control procedures.

- 3. Performing additional random procedures to determine compliance with the program. Procedures will include all aspects from receiving through shipping and may include observation, review of records, or both. All records from an entire lot of product will be reviewed on a periodic basis. Reviewed records will be signed and dated.
- 4. If there is noncompliance with EU requirements or with the establishment's control program, the IIC will notify management and request correction of the deficiency. If a deficiency is not corrected, the IIC will withhold the EU health mark label (or brand). The labels (or brand) will be returned to the IIC and secured until correction is made. The IIC will document the noncompliance.
- 5. If repeated deficiencies occur, or a non-compliance is not corrected in a reasonable time period, the Export staff at the Technical Service Center shall be notified through supervisory channels.

### XIII. SOURCE OF RAW MATERIAL

Cutting and processing plants intending to prepare products for export to the EU must source the raw meat or poultry from EU approved slaughter establishments. The raw material must be eligible for export to the EU and bear the EU health mark. Identification and segregation of the raw material must be acceptable to the IIC.

Raw material may be imported for the purpose of EU production provided it bears the EU Health Mark, as described above, and is eligible for importation into the United States.

### XIV. HEALTH MARKS

- A. Health mark labels must be applied to each carton of product in such a manner that the health mark label is destroyed when the package is opened. The health mark label must bear the following information:
  - 1. an oval mark at least 2.5 in (6.5 cm) wide by 1.8 in (4.5 cm) high.
  - 2. within the oval:
    - a. in the center the establishment number.
    - b. in the upper or lower part the letters USA.
    - c. the letters must be at least 0.3 in (0.8 cm) high and the numbers should be at least 0.4 in (1 cm) high.
  - 3. a sequential serial number that is unique to each health mark label for that establishment.
- B. The health mark labels and brands must be kept under security by the IIC in a manner analogous to USDA brands. The IIC is responsible for maintaining an inventory of the health mark labels. Health mark labels should be given to plant management only while eligible products

are being identified and marked and only for the length of time necessary to complete the task.

C. Meat carcasses must be stamped with ink or hot branded using a stamp or brand with the specifications described in A.1. and A.2. Those carcasses weighing more than 143 pounds (65 kg) must be stamped in at least the following places: external surface of the thighs, loins, back, brisket, and shoulder. Other carcasses must be marked in at least four places: on the shoulders and on the external surface of the thighs. Carcass stamping is not required if the carcasses are slaughtered, cut and packaged within the same establishment. Plant management must assure, to the satisfaction of the IIC, that proper identification of eligible carcasses is maintained throughout the establishment.

### XV. FINLAND AND SWEDEN

Finland and Sweden require additional microbiological testing of fresh veal, beef, pork, and poultrymeat for salmonella prior to export certification. The sampling methods and number of samples to be taken varies with the class of product and the size of the consignment. Specific information regarding sampling methods, number of samples to be taken, and the testing methodology is available from the Export staff of the Technical Service Center.

The additional testing is not required if the fresh veal, beef, pork or poultrymeat is destined for the manufacture of meat products in Sweden or Finland.

### XVI. COMPLIANCE OVERSIGHT BY FSIS

### A. Production modes

Plants must be in an EU production mode whenever producing for EU export. It is not necessary that establishments be in an EU mode when producing for non-EU markets. However, all establishments must provide an EU mode control program to the IIC to assure that all EU requirements are met before beginning EU production. The plant must be in the EU mode during prescreening by FSIS and during any EU review. The key role in assuring compliance with the requirements for export to the EU is with the IIC. If an approved plant is not in compliance with the EU requirements, the IIC should withhold the use of the EU health mark label (See Section XIII.) and notify plant management of the non-compliance. The EU health mark label should be returned to the secured location until the deficiency has been corrected. Product not bearing the EU health mark label was not produced according to the requirements for export to the EU and is not eligible for export certification to an EU member state.

### XVII. DOCUMENTATION - LIST OF REQUIRED CERTIFICATES

A. Only meat and poultry and meat and poultry products produced at approved establishments that meet the requirements described herein may be certified for export to the EU. All certificates for EU except FSIS Form 9060-5 must have a preprinted blue seal. All EU documents must be signed by an FSIS Veterinarian in a color other than black.

#### B. Fresh meat

FSIS Form 9060-5 Export Certificate of Wholesomeness

FSIS Form 9180-2 Public Health Certificate

FSIS Form 9180-1 Animal Health Certificate

FSIS Form 9180-3 Certificate of Authenticity for high quality beef or veal, if requested

In addition to the above certificates the following statement must be included in the "Remarks" section of FSIS Form 9060-5, Export Certificate of Wholesomeness, for fresh/frozen beef, pork, beef offal, and pork offal:

"The Meat is derived from animals which have been treated in the slaughterhouse before and at the time of slaughter or killing in accordance with the relevant provisions of Council Directive 93/119/EEC".

## C. Horsemeat

FSIS Form 9060-10 Horsemeat Export Certificate

FSIS Form 9180-2 Public Health Certificate

FSIS Form 9180-1 Animal Health Certificate and either:

- 1. FSIS Form 9205-1 Certificate Relative to a Test of Trichinae in Horsemeat, or
- 2. FSIS Form 9205-2 Certificate Relative to the Cold Treatment of Horsemeat.

## D. Fresh poultry

FSIS Form 9060-5 Export Certificate of Wholesomeness

FSIS Form 9180-8 Public Health Certificate for Fresh Poultry Meat

FSIS Form 9180-6 Animal Health Certificate for Fresh Poultry Meat for Human Consumption

## E. Meat Preparations (including poultrymeat preparations)

FSIS Form 9060-5 Export Certificate of Wholesomeness

FSIS Form 9180-10 Public Health Certificate for Meat Preparations

- 1. For red meat preparations, FSIS Form 9180-1 Animal Health Certificate
- 2. For poultrymeat preparations, FSIS Form 9180-6 Animal Health Certificate for Fresh Poultry Meat for Human Consumption

## F. Meat Products (from red meat)

FSIS Form 9060-5 Export Certificate of Wholesomeness

FSIS Form 9180-13 Public Health Certificate for Meat Products Intended for Export to the European Community

FSIS Form 9180-11 (English) or 9180-12 (English/German) Animal Health Certificate for Meat Products Intended for Consignment to the European Community

G. Meat Products (from poultrymeat and game meat)

FSIS Form 9060-5 Export Certificate of Wholesomeness

FSIS 9180-9 Public Health Certificate for Meat Products Obtained from Poultry Meat, Farmed Game Meat, Wild Game Meat and Rabbit Meat

FSIS Form 9180-11 (English) or 9180-12 (English/German) Animal Health Certificate for Meat Products Intended for Consignment to the European Community

- H. Other products of animal origin Member state certification should be issued pending determination of EU certification requirements.
- I. Fresh meat of ratites Member state certification should be issued pending determination of EU certification requirements.
- J. Fresh meat of wild boar

FSIS Form 9060-5 Export certificate of Wholesomeness

FSIS Form 9180-XX Animal and Public Health Certificate for Meat of Farmed "Wild Swine" Intended for Consignment to the European Community (this certificate is under development at this time and will be available in the near future.)

## K. Animal casings

1. Depending upon the source of the casings, obtain one of the following certificates:
a. FSIS Form 9060-7, Animal Casings Export Certificate for Countries Requiring
Ante-Mortem, Post-Mortem, and Fit for Human Food Statements (for casings

derived from animals slaughtered in the U.S., or

- b. FSIS Form 9060-17, Animal Casing Export Certificate for Countries Requiring Ante-Mortem, Post-Mortem, and Fit for Human Food Statements (for casings derived form animals slaughtered in the U.S. and processed in Mexico), or c. FSIS Form 9060-18, Animal Casings Export Certificate for Countries Requiring Ante-Mortem, Post-Mortem, and Sound and Clean Statements (for casings imported into the U.S.).
- 2. The following statement must be included in the "Remarks" section of the health certificate or on an accompanying FSIS letterhead certificate:
- "The casings have been produced in accordance with the conditions laid down in Annex C, Chapter III of Directive 77\99\EEC."
- 3. FSIS Form 9180-7 Animal Health Certificate for Animal Casings Intended for Dispatch to the European Union. Note: The serial number from the health certificate used above must be placed in the block labeled "Reference Number of the Health Certificate" on FSIS Form 9180-7.

### XVIII. PLANT APPROVAL PROCESS

## A. Under the new agreement:

- 1. The Export Staff of the Technical Service Center (402) 221-7400 will provide technical assistance regarding the provisions of the agreement to plant management and FSIS personnel. In addition, U.S. Meat Export Federation (303-623-6328) and U.S.A. Poultry and Egg Export Council (770-413-0006) may provide technical assistance to plant management interested in EU approval.
- 2. Plant management seeking EU approval should complete and submit FSIS 9080-3, Establishment Application for Export, to the Export Staff of the Technical Service Center through FSIS supervisory channels. The Technical Service Center may perform on-site visits to confirm that an establishment complies with the conditions of the new agreement.
- 3. Plants that comply with the conditions stated herein will be submitted to the EU for approval. FSIS will certify to the EU that U.S. meat and poultry establishments comply with the appropriate conditions as outlined above. The EU will approve and list the plants in a timely manner. Plants may begin producing for export to the EU under the conditions of the new agreement on the date of EU listing.
- 4. The EU has the right to audit approved plants to confirm that they comply with the conditions of the agreement.

# B. Partial approvals - Applies to red meat only

Establishment management seeking approval of only the part of their plant that processes product for EU export can request partial plant approval for certain products under the following conditions:

- 1. The establishment shall develop a Quality Assurance (QA) program which addresses the mode of operation, the identification of product, and the segregation of the product from receiving to shipping. Establishments which want to apply for partial approval must meet the facility requirements in the approved areas to ensure physical and/or time separation of approved and non-approved products.
- 2. The QA program shall include an establishment monitoring schedule and a log to document both monitoring actions and corrective actions.
- 3. The QA program shall be acceptable to the IIC and be available and acceptable to the EU auditor.
- 4. The IIC shall monitor the establishment's application of the QA program and document such monitoring and ensure correction of deficiencies.
- 5. The establishment must be able to demonstrate the program during an audit. All relevant documentation must be available.
- C. Animal casing plants Casing operations must be FSIS inspected. Plants not already under FSIS inspection for other products must apply for a grant of inspection, be approved for voluntary inspection, then apply for EU approval by submitting FSIS Form 9080-3 to the Export Staff at the Technical Service Center. In addition to meeting FSIS requirements, these plants must comply with special EU requirements such as medical certification, water testing, facility requirements such as the color of walls, the use of wood pallets as well as the specifications for the EU Health Mark described previously in this document.

### XVIV. LISTS OF ELIGIBLE PLANTS

Lists of eligible plants for the various product categories are available through the Export Library. Plants must meet all EU requirements in addition to being listed on the appropriate list. Contact the FSIS Technical Service Center, Export Staff for assistance at (402) 221-7400. EUREQ7 07/21/2000

Attachment 1	
E	U Pork Heart Data Sheet
Establishment No.	
Week of	
Date of Inspection	
Gross Pathological Lesions:	
IIC Signature	

## Questions And Answers For The European Union Requirements

## II. FACILITY, EQUIPMENT, PROCEDURES

# 1. Does packaging material have to be shrink wrapped when received and while in storage?

There is no specific requirement for shrink wrapping, however, the packaging material must be stored and handled in a sanitary manner. A plant may choose to shrink wrap as an aid to sanitary storage and handling.

## 2. Is cove molding required under the new agreement?

No. Neither cove molding nor the 45 degree slope will be required. However, the wall and floor junctions, as well as the cracks, must be properly sealed to maintain sanitary conditions.

## 3. Do the wall and floor junction requirements of II.B. apply to all rooms of the plant?

No. This requirement only applies to rooms where product is being produced, handled, or stored.

# 4. Does packaging material for EU destined product have to be stored separately from packaging material used for products destined for other markets?

No. EU packaging material does not have to be stored separately. It can be stored in the same room as other packaging material.

### 5. When must the plant phase out the use of wooden pallets?

There is no specific deadline for the phase out of wooden pallets, however this should be a goal of all establishments shipping to the EU.

### 6. If plastic slip sheets are used on wooden pallets, does the 3 meter rule apply?

## 7. Will there be any flexibility offered with regards to the 3-meter rule?

No. This 3-meter rule was a compromise with respect to the use of wooden pallets. The EU would ideally like plants to use only plastic pallets. The best agreement reached was that wooden pallets would be phased out over time, but until then, the 3-meter rule will apply.

### 8. Would it be acceptable to completely enclose the pallet in plastic?

The top must be covered. If a plant chooses to go beyond this requirement, it must be done in a sanitary manner.

## 9. Can packaging materials be stored on wooden pallets without a plastic slip sheet?

Yes. The plastic slip sheet requirement only applies to exposed product areas.

## 10. Must cleaning and other materials be stored separately from packaging materials?

Yes.

## 11. Can product in combo bins be stored in coolers or freezers with boxed product?

Yes, if the combo is covered with a lid or the plastic combo liner is closed over the product.

### 12. Is sterilization the correct term in II.K.?

A better term to use is "sanitization". However the key to compliance is using water of the correct temperature.

### 13. Do sanitizers have to have an overflow mechanism?

No. Sanitizers must be maintained and used according to FSIS requirements. Overflows can be an option for a plant to maintain sanitizers in an acceptable manner.

# 14. Are the sterilization (sanitization) procedures for utensils and implements applicable only when handling raw meat?

No. These procedures are to be used in handling any meat/poultry product eligible for export to the EU.

## 15. Will the "washing" of meat dropped on the floor be permitted?

FSIS regulations will apply in this situation.

# 16. Previously, we could not pack offal products in same room as other products being packed. Is this an acceptable practice now?

Yes. However, edible and inedible product cannot be packed in the same room. Also, packed product may not be stored in coolers with exposed product.

### III. EMPLOYEE MEDICAL CERTIFICATION

### 1. What kinds of medical records must be available to the auditors?

The medical certification statements must be available. The actual medical examination records are not required to be available.

# 2. How does the reviewer know that a physician's assistant or a registered nurse is under the supervision of medical doctor?

The establishment must be able to demonstrate this.

### 3. What needs to be included in the medical examination?

These requirements are left to the discretion of the medical official signing the certification statement. The EU does not mandate specific disease testing (e.g. hepatitis, tuberculosis, etc.) Specific disease testing is left up to the professional judgement of the medical professional that is signing the certification.

### IV. WATER TESTING

# 1. Must you maintain the EU water and residue testing programs even if you are not currently exporting to the EU?

Yes. This is part of the plant approval process.

## 2. Why does the EU insist on continuing the water and residue testing programs?

These issues are still being discussed with the EU delegation. However, in the interim, the programs, as outlined in the requirements will continue.

# 3. If our water testing program is currently approved for the EU, must we get this program reapproved?

No. FSIS water potability requirements currently are not an acceptable alternative to EU water testing requirements.

## 4. What is permissible as acceptable chlorination levels in water?

The levels acceptable under FSIS regulations for potable water.

### V. ANTEMORTEM INSPECTION

## 1. Are there any additional requirements for antemortem inspection of poultry?

No. FSIS requirements apply.

#### VI. SWINE HEART INCISION

# 1. Are 6 swine hearts required to be incised and examined each week even though the establishment may not be producing for export to the EU?

Yes. If an establishment is on the approved plant list, the hearts must be examined.

# 2. How is swine heart incision affected if a plant does not slaughter for some period of time during the year?

Each approved establishment must incise and examine 300 hearts per year. The 6 hearts per week requirement is based on the plant operating on a continuous basis. The number of hearts per week should be increased to assure that 300 are examined annually if the plant does not slaughter on a weekly basis.

## 3. Who can perform the heart inspection?

The inspection must be done by an FSIS VMO. It may be done by the IIC VMO, the antemortem VMO or by a circuit supervisor VMO.

### VII. TRICHINAE TREATMENT

# 1. With respect to trichinae treatment, are processed products subject to EU requirements?

Processed products containing pork must be produced from raw pork meat that complies with the EU requirements, including trichinae treatment.

### 2. Will the EU approve trichinae testing labs?

EU directive 77/96/EEC provides the methodology for trichinae testing. AMS provides analyst training and certification that the laboratory complies with the testing methodology indicated in this directive. The EU does not provide individual laboratory certification.

### VIII. ANTIMICROBIAL TREATMENT

1. Will it be acceptable to "turn off" or discontinue the use of an antimicrobial rinse for product being prepared for domestic commerce when moving into an EU mode of production?

Yes, provided the action is effective in preventing product contact of the antimicrobial rinse.

### IX. POULTRY CHILLING

1. Is the selection and testing of poultry carcasses and subsequent report of the assessment and results to Export Staff /Technical Service Center optional when an establishment chooses to use an alternative chilling system as outlined in IX.B.?

No. The establishment <u>must</u> select, test, and report to use an alternative system.

2. Will the EU have to validate alternative chilling systems?

No. FSIS will do the validation.

3. Is the alternative chilling system option a complete substitute for IX.A.?

Yes. None of the requirements in IX.A. apply, if the establishment complies with the requirements of IX.B.

4. Is there a specific time for chilling poultry to 40°F?

There are no special chill-time requirements for EU, but poultry must reach 40°F in the shortest time possible after slaughter and at least meet FSIS requirements according to 381.66.

5. Can poultry carcasses be hot deboned?

Carcasses weighing up to 6 lb. that begin the chilling process must reach 40°F before they can be deboned. Carcasses that weigh more than 6 lb can be hot deboned in accordance with FSIS regulations.

### X. RESIDUE TESTING

### 1. Is there a residue testing requirement for poultry?

FSIS is currently evaluating the EU residue-testing requirements for poultry against the compounds tested for in the FSIS National Residue Testing Program. Any additional requirements will be reflected in the EU Requirements.

# 2. Will the EU "Member States" be allowed to residue-sample U.S. product when it enters their country as they sometimes do now?

Yes. As we do in the U.S., monitoring samples for residue testing can be sampled by the member states at port of entry.

## 3. Are further processors subject to maintaining a Residue Testing Program?

No. Only slaughter plants. Processors will receive EU product in containers sealed by the oval health label. When this label is broken and the product further processed, the processor will reapply their own oval health label prior to exporting the product to the EU. Also, keep in mind, combo bins may be used to move EU destined product from one plant to another within the U.S., but are not acceptable to use in exporting product to the EU.

## 4. Is a Residue Testing Program required for beef exports?

Yes. Red meat slaughter plants need to participate in the AMS residue Residue Testing Program, separate from the Export Applications. Also, if plants change labs, it's their responsibility to notify the Export Staff at the Technical Service Center.

### XI. NON-HORMONE TREATED BEEF AND VEAL

### 1. What does HFC mean?

Hormone Free Cattle

### 2. What does NHTC mean?

Non-Hormone Treated Cattle

### XII. SOURCE OF RAW MATERIAL

1. Are only U.S. slaughter plants that are EU approved eligible to supply raw materials to U.S. processing plants or can raw materials be obtained from any EU approved plant worldwide?

Raw material may be imported for the purpose of EU production provided it bears the EU Health mark, as described in the EU Requirements, and is eligible for importation into the United States.

### XIV. FINLAND AND SWEDEN

### 1. Can the additional requirements of Sweden/Finland be included in the export library?

Yes. This information will be added.

### XV. FSIS OVERSIGHT

1. Is there a requirement for veterinary supervision of processing plants and cold storages?

No. FSIS domestic requirements apply.

XVII. PLANT APPROVAL PROCESS

1. Do processing plants have to meet these requirements?

Yes. All slaughter, processing and cold storage establishments must meet these requirements.

2. Is the completion of FSIS 9080-3, Establishment application for Export, mandatory for those establishments seeking EU approval?

Yes.

3. Do establishments currently on the EU approved establishment list or on EU member country lists have to reapply?

Yes. These plants must submit FSIS 9080-3.

4. Please expand upon "deficiencies" with respect to gaining a "partial" versus "full" plant approval. For example, if a plant applies for "full" approval, but are found deficient in a certain area, can that plant receive "partial" approval?

Yes. If a plant applies for "full" approval, and deficiencies are found that would prohibit granting a "full" approval, then depending on what the deficiencies are that are found, a "partial" approval may or may not be permissible. Remember, a plant will be reviewed based on the information provided on the Application for Export. Following the review, the plant will be advised regarding any deficiencies and whether or not a "partial" approval would be permissible.

5. If the slaughter operation is approved but the processing operation is not, can I request a "partial" approval?

Yes. This will be discussed at the time of the exit interview.

6. Why is there a "rendering" check-off block on the FSIS Form 9080-3?

This form will be used for all countries requiring plant approval, not just for the EU.

7. Since industry will be charged for these reviews, can industry transport the government reviewers on corporate jets?

No.

## 8. How long will it take for EU confirmation to allow plants to begin exporting?

Once FSIS certification is submitted, the EU has a 21-day approval period for new plants.

## 9. Will plants still be subject to EU "Member State" requirements?

No. This agreement is a harmonized animal and public health plan. There will be no additional animal and public health requirements imposed by the "Member States".

## 10. Who will maintain the EU Approved Plant List?

FSIS will submit recommendations, and maintain the List.

### 11. Can we select the reviewers?

No.

## 12. Does the EU have to review US plants prior to approval?

No. FSIS will review the facility prior to certifying the plant to the EU to assure compliance with EU requirements. The EU will then approve plants based on the information provided by FSIS. Further, the EU will carry out verification procedures, which may include an audit of a plant that has been approved.